DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 24 1999

WARNING LETTER

Ref: OC:I1-1836

Mr. H.D. Kim
General Manager, Quality Control Team
Anam Electronics Co., Ltd.
645, Sungkok-Dong
Ansan-City, Kyungki-Do
KOREA

Dear Mr. Kim:

On September 20, 1999, Mr. Joseph Teixeira and Mr. Emir Galevi of the United States (U.S.) Food and Drug Administration (FDA) conducted an inspection of your television products manufacturing facility. The FDA inspectors reported several serious deficiencies found in Anam Electronics' quality control and testing program. Based on their findings, the Center for Devices and Radiological Health (CDRH) believes that your quality control and testing program is not adequate to assure that television products will comply with the Federal performance standards and other applicable regulations. A copy of inspection report is enclosed.

Therefore, under the authority of Section 534(h) of the U.S. Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C - Electronic Product Radiation Control (21 CFR 1010.2)), CDRH hereby disapproves the quality control and testing program for Anam Electronics Co., Ltd., effective immediately. This program disapproval is designated for all television products being produced for U.S. commerce.

This disapproval of the testing program means that your firm is prohibited by Sections 534(h) and 538 of the Act from:

1. certifying the electronic products manufactured under the disapproved testing program,

2. introducing or importing products into U.S. commerce which bear false and misleading certification, that is, products certified under the testing program which as been disapproved, and

3. introducing or importing into U.S. commerce any product which does not have the certification label permanently affixed to the product, as required by 21 CFR 1010.2.

Under Section 536(a) of the Act, entry or importation into U.S. commerce must be refused for any electronic product if it appears that the product fails to comply with the applicable standards, or the manufacturer's testing program has been disapproved.

The FDA may initiate regulatory action against any person who violates Section 538, including an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

The Act also prohibits anyone, including the importer, from failing to make any report required pursuant to Section 537(b) and from failing to furnish or preserve any information required pursuant to Section 537(f).

The following deficiencies have been brought to the attention of Anam Electronics' quality control and testing personnel:

Failure to Maintain Adequate Instrumentation, Maintenance and Calibration Program

1. Anam Electronics Co., Ltd., claimed that the qualitative x-radiation survey meter, [redacted] was broken and out for repair. However, no evidence was provided to show that Anam Electronics actually owned a [redacted] meter.

2. The [redacted] quantitative x-ray survey meter was not working properly. The needle was moving erratically but the test technician continued to use the defective instrument. This instrument is used primarily for compliance x-radiation measurement as required by 21 CFR 1020.10.

3. The backup [redacted] was out of calibration and could not be used.

4. The calibration records for the [redacted] and the [redacted] were not made available to the inspectors.

5. The firm has no written plan or procedures in case the [redacted] or [redacted] meter is out for calibration or repair. There are no working backup meters.

Inadequate Phase III X-radiation Compliance Testing

6. The bumpers of the [redacted] were not placed directly on the side of the television product being tested. The instrument was held 5 cm from the product. This is not the correct way to use this instrument. The technician apparently lacked the training on the proper usage of the x-radiation measurement.

7. The x-ray test for the model number CTVG-5463GVC should have been performed at a higher beam current. The technician did not adjust the service and user controls to maximize x-radiation emissions, that is, so the power point setting for x-radiation survey is in the region of the chassis power curve that most closely approaches the 0.5 mR/hr isoexposure rate limit curve for the cathode ray tube, or most exceeds it. An adequate engineering analysis is needed to determine this point.

8. Anam Electronics Co., Ltd., used the rejection criteria of [redacted] mR/hr as stated in their product reports, however, the x-radiation procedures posted on the wall for Model CT13D80/CT19D80 indicated a rejection criteria of [redacted] mR/hr.

Inadequate Recordkeeping

9. The Phase III x-radiation test record needs additional information. It needs to include all test instruments used and their serial numbers.

To resolve this program disapproval warning letter, Anam Electronics Co., Ltd., must:

1. Provide a video tape of all Phase III x-radiation testing procedures, including (a) equipment set-up (volt meter, ammeter, input line voltage meter, etc.), the x-radiation survey meters ([redacted] and [redacted]), (b) actual procedures performed on a television product including worst component failure selected for the test, user and service controls to be adjusted, test pattern used, measurement of high voltage and beam current, B plus, operational check and correct handling of the qualitative and quantitative x-radiation survey meters, scan patterns, data to be noted and recorded on the final test record, tolerances and rejection limits, and procedures to be followed in case any reading is out of tolerance or over the limit. Step-by-step instructions during Phase III x-radiation testing must be open captioned in English on the video tape.

2. Submit a training plan for qualifying all test technicians in proper usage of test instruments and proper test techniques.

3. Provide calibration records for test equipment used especially the [redacted] and the [redacted] and [redacted]

4. Anam's quality control and testing program must be inspected by an independent consultant or a firm who will observe the actual quality control and testing procedures and compare with those reported in the product report. This independent inspection report should be furnished along with any response concerning this program disapproval.

All of the information requested above must be submitted to the Center for Devices and Radiological Health (CDRH) in order for CDRH to determine that Anam Electronics Co., Ltd., is in compliance with the Act, that the subject products comply with the Federal Performance Standard for Television Receivers, 21 CFR 1020.10, and that the testing program is in accord with good manufacturing practices.

Anam Electronics has submitted a television product report for review after FDA's inspection. We are returning this product report to you for lack of proper x-radiation survey instrumentation found during WEAC's inspection and in the product report. If you do not have proper testing equipment how can you or anybody be assured of adequate testing. We suggest that you redo your engineering analysis for all current chassis families after you have satisfactorily provided the requested information above. CDRH must know that you fully understand the Federal Performance Standard for Television Products, 21 CFR 1020.10, and that you have instrumentation capable of doing such testing.

A copy of this letter will be posted on the FDA's world wide web home page under Monthly Import Detention List and Warning Letters: http://www.fda.gov.

Please submit your response regarding the deficiencies cited above within 15 days of receipt of this letter. It should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance (HFZ-342)
Division of Enforcement III
2098 Gaither Road
Rockville, MD 20850

In your response, please reference case and this letter. If you have any questions, you may contact Ms. Debra Clingan at (301) 594-4654, or by facsimile at (301) 594-4672.

Sincerely yours,

Gladys Rockwell for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: 10/12/1999 Inspection Report of Anam Electronics Co., Ltd.